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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,795	03/10/2004	Carlos R. Plata-Salaman	ORT-1575CON	4508
27777	7590	09/21/2009	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			LEWIS, AMY A	
			ART UNIT	PAPER NUMBER
			1614	
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			09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,795	Applicant(s) PLATA-SALAMAN ET AL.	
	Examiner Amy A. Lewis	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 25 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 25 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' arguments, filed 9/11/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-21, 24, 25, and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6103759 (to Choi et al.) in view of U.S. Patent No. 5474990 (to Olney).

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This rejection is moot regarding claims 21, due to amendment, and 24 as it has been cancelled. The rejection is **maintained** over claims 1-20, 25, and 32 for the reasons of record and further below.

Applicants argue that the amendment to claim 21 obviates the rejection. This is not persuasive regarding the remaining claims as they still read upon treatment of stroke induced hypoxia/ischemia.

Applicants argue that the primary disclosure of the Choi et al reference is that the “disclosed compounds are anticonvulsants” and classifies the teaching to treat stroke as “an afterthought” (see Remarks p. 7).

This is not persuasive because prior art references are to be considered in their entirety, are used for all that they teach, and are not limited to use of only preferred embodiments or Examples. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See MPEP 2141.02 and *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Moreover, the Choi et al. reference teaches stroke as a preferred embodiment for treatment with the recited compound (see col. 7, lines 11-15).

NEW REJECTION NECESSITATED BY AMENDMENT:

2) Claims 1-21, 24, 25, and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6103759 (to Choi et al.) in view of Zaidi et al. (*J Am Coll. Cardiol* 2000, Vol. 36(1), pages 181-184).

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Choi et al. teach the elected compound (see col. 8, Table I, entry 3). The cited table also teaches a dose of 50.0 mg/Kg. The reference also teaches that the compound can be used for the treatment of diseases of the central nervous system, particularly “convulsions, epilepsy, stroke and muscle spasm” (see. col. 7, lines 11-15).

While Choi et al. do not teach injury caused by hypoxia-ischemia, however Zaidi et al. teach many patients with cardiovascular syncope, described as abnormal movements due to cerebral hypoxia, experience convulsive blackouts (see abstract and p. 181). The reference also teaches that “complete arrest of cerebral circulation has been shown to be highly associated with convulsion” (p. 183, Discussion).

Thus treatment of the convulsions and epilepsy as administered in Choi et al. would also treat the accompanying hypoxia that occurs with the convulsions. It would have been obvious to one of skill in the art at the time the invention was made that since the convulsions and epilepsy accompany hypoxic-ischemic conditions and resulting injury, treatment with the instantly claimed compound would also treat hypoxia-ischemia occurring due to the convulsions. Therefore the invention as a whole is *prima facie* obvious.

MODIFIED GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-21, 24, 25, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of acute neurodegenerative disorders associated with abrupt insult resulting from hypoxia-ischemia selected from cerebrovascular insufficiency, cerebral ischemia and cerebral infarction by administration of the compound of Formula (Ib) S-enantiomer, does not reasonably provide enablement for *prevention* of these acute neurodegenerative disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection is maintained and modified for the reasons below.

Applicant has amended the claims to remove the term “preventing”. As stated previously, Applicant demonstrates *treatment* of transient cerebral ischemia in the rat MCAO model by administration of by administration of the compound of Formula (Ib) S- enantiomer (the elected compound). See Example 2, pages 20-22, which show significant reduction in infarct volume with administration of the elected species of compound. However, Applicants examples have not demonstrated *prevention* of neuronal cell death as a result of treatment. Demonstration of *prevention* of the disease in a mammal would require more extensive evidence to demonstrate possession (See MPEP § 2164.03). It is well established in the courts that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved”, and physiological activity is generally considered to be an unpredictable factor, See *In re Fisher*, 166 USPQ 18, at 24 and MPEP § 2164.04. *Additionally*, the specification states (in para. [0003]) that “prevention of neuronal cell death is required for the treatment of both acute and chronic neurodegenerative disorders”. Thus, Applicant continues to define treatment as including

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prevention, which is not sufficiently described to enable a person skilled in the art to which is pertains to make or use the invention commensurate in scope with the claims without undue experimentation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614